DEC 2 9 2000

K003240

SUMMARY OF SAFETY AND EFFECTIVENESS

SPONSOR: Biomet, Inc.
P.O. Box 587
Airport Industrial Park
Warsaw, Indiana 46581-0587

CONTACT PERSON: Tracy J. Bickel

DEVICE NAME: Biomet® External Wrist Plate

DEVICE CODE: 87 JDW

CLASSIFICATION NAME: Pin, Fixation, Threaded (888.3030)

INTENDED USE:
Stabilization of open and/or unstable fractures of the distal radius, where soft tissue injury may preclude the use of other fracture treatments such as IM rodding, casting, and other means of internal fixation.

DEVICE DESCRIPTION:
The device is an external fixator made of the radiolucent polymer, polycarbonate. The fixator is a non-bridging device, which means that it does not cross the wrist. Which will give patients the ability to utilize wrist function. There are many tapped holes in the plate allowing pins of either 3mm or 1.5mm diameter to be inserted through into the bone and held in place with a special bolt. The special bolt has a collet on the tip of the bolt that compresses onto the pin as it is tightened. The plate also has the ability to connect a side piece, which will allow 1.5mm pins to be inserted into the side of the wrist for additional fixation. The external fixator is anatomical which is determined by which side the side piece can be connected to. The device will be sold as a sterile kit. Everything needed to for implantation will be sold in a kit, fixator, pins, and instruments.

POTENTIAL RISKS:
The potential risks associated with this device are the same as with any joint replacement device. These include, but are not limited to:

Fracture of the component	Delayed wound healing	Bone fracture
Dislocation	Excessive wear	Tissue growth failure
Implant loosening/migration	Blood vessel damage	Metal sensitivity
Soft tissue imbalance	Nerve damage	Infection
Deformity of the joint		

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SUBSTANTIAL EQUIVALENCE:

Direct comparison was made with the following predicates:

510(k)	Manufacturer	Device Name
K982982	Biomet, Inc.	Biomet® Mini-Fixator
K971755	Howmedica Corp.	Hoffman II® Compact ™

Biomet® Mini-Fixator is a registered trademark of Biomet, Inc.
Hoffman II® Compact™ is a registered trademark of Howmedica Corp.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Ms. Tracey J. Bickel
Regulatory Specialist
Biomet, Inc.
P.O. Box 587
Warsaw, Indiana 46581-0587

Re: K003240
Trade Name: Biomet External Wrist Plate
Regulatory Class: II
Product Code: LXT and KTT
Dated: October 16, 2000
Received: October 17, 2000

Dear Ms. Bickel:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K003240
Device Name: **External Wrist Plate**
Indications for Use:

Stabilization of open and/or unstable fractures of the distal radius, where soft tissue injury may preclude the use of other fracture treatments such as IM rodding, casting, and other means of internal fixation

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use_____ OR Over-The-Counter Use_____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

for Mark N Milhern

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K003240